

EXHIBIT D

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Erik Wagner
V.P., Research and Development,
Spine Concepts, Inc.

Dear Erik,

Thank you for your letter of [redacted] sincerely apologize for this late response. I'm pleased to hear, from Brian, that there was a favorable decision regarding the development of the Unidirectional Dynamic plate! You raised a number of important questions in your letter, which I'll attempt to address in this letter.

1. You are concerned about the need for the need for either the male or the female member of the plate to be able to flex/deflect for the coupling of the ratchet mechanism to interlock. This would compromise the stiffness of the plate, and that there are limited number of materials we can work with. This is a legitimate concern. I don't think we can tolerate compromising the stiffness of the female member. The male component may be partially slit in the middle to allow convergence as it negotiated the teeth of the female member. The other option is to have both members stiff but have a retractable peg at the mouth of the female or the tip of the male member. The peg is protracted by a spring mechanism and forced to retract by the pressure from the opposite member. You could have more than one peg on each side depending on forces they can tolerate, and without compromising the strength of the components. Please see the attached sketch.
2. You are also concerned about the stability of this design particularly in lateral bending and axial rotation. It has now been proven in fracture fixation that a small amount of movement stimulates osteogenesis and speed fracture healing. Hence, the proliferation of dynamic external fixators and dynamic intramedullary rods. The prevalence of non-union under a rigid plate of a multilevel fusion is what is prompting the search for dynamic plates. So a small amount of motion – *micro-motion* – at the graft-host interface is good. This plate is load sharing, hence a significant component of forces transmitted through the fused segment will actually go through the graft itself and its torsional resistance should protect the plate from undue stresses.

3. You are concerned about the unidirectional plate increasing the load on the graft. Remember before the advent of cervical plates, and even to day, some of us prefer to graft the cervical spine without plating. In those circumstances the weight of the body above the fused segment is transmitted entirely through the graft. Sometimes the graft breaks and some times it dislodges from the graft bed under pressure. With the unidirectional plate, there will be a set allowable telescoping per graft-host interface (we can the data bone necrosis at fracture site as a guide). Therefore, with this plate, there is a controlled loading and protection from graft fracture and dislodging of the graft, thus combining the virtues of free-standing graft and plate fixation while minimizing their individual deficit.
4. You are concerned about clicking in the neck as the ratchet lock. I don't think is will be a concern for most patients. There should not be more than 2 – 4 clicks in the lifetime of a plate. Most of the clicking will come in the early post-operative phase while the compression of the graft is occurring. Once the graft is stable there should no further telescoping. It would be preferable to use a fibular ring allograft or autograft with this plate. The graft should fit snugly and should withstand dislodging effort by the surgeon after releasing traction on the cervical spine, on then should the plate be applied.
5. I don't think I understand your question regarding the increments! Locking should be at 0.5 to 1-mm intervals. The intervals should be uniform. We should determine the pitch of the locking teeth based on cadaver studies, and the range of compression allowable on fracture studies as well as cadaver studies. The idea is to achieve compression enough to facilitate healing of the graft without incurring a kyphotic deformity

The result of fusion without plating at one level is excellent, but an increasing number of surging will plate using one argument or another to justify the decision. If the cadaver studies can show this design can withstand a comparable range of forces as its competitors it will be ideal plate for 2 or more level fusions.

I'll arrange to visit your plant with Brian in the near future.

Yours most sincerely,

Said G Osman.

Cc: Brian Smith
Colleen Turner, Product Manager - Cervical Products.